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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,462	05/26/2000	Stephen Fox Heinemann	SALK1590-3	2034

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/580,462

Applicant(s)

Heinemann et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 8, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 34-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-44 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1) Claims 7 and 34 to 44 are pending in the instant application. Claims 5, 6, 8, 9, 11, 12 and 14 to 33 have been canceled and claims 34 to 44 have been added as requested by Applicant in Paper Number 10, filed 8 October of 2002.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 October of 2002 has been entered.

5) The figures filed on 8 October of 2002 clearly fail to meet the requirements of 37 C.F.R. § 1.84(U)(1), for those reasons of record in section 2 of Paper Number 6. **Correction is required.**

6) Claim 7 would be allowable if it complied with 37 C.F.R. § 1.84(U)(1).

7) Claims 35 and 38 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependant claim can not

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conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III. Claim 34, from which claim 35 depends, for example, is limited to a polynucleotide encoding a protein. Claim 35 encompasses not only a polynucleotide encoding a specific protein but also the “complement thereof”. Because the “complement” referred to in claim 35 does not infringe claim 34, claim 35 is not properly dependant therefrom.

8) Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim expressly requires the deposited material recited therein to make the claimed invention. Applicant, their assignee or their agent needs to provide a declaration containing the following:

The identification of the declarant.

A statement that a deposit has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

A statement that the deposited material has been accorded a specific, recited, accession number.

A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited

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microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

A statement by declarant that all statement made therein of declarant's knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternately, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) **and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.** Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession number) number, name and address of the depository, and the complete taxonomic description.

9) Claims 34 and 36 to 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for those reasons of record as applied to claims 5, 8, 9 and 11 to 17 in section 6 of Paper Number 6 and claims 5, 8, 9, 11, 12 and 14 to 27, 31 and 32 in section 8 of Paper Number 9. As stated therein, the instant specification provides an adequate written description of an isolated nucleic acid encoding the amino acid sequence

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presented in Figure 7B of the instant application, and nothing else. These claims recite a plurality of structural and functional limitations. However, one of ordinary skill in the art of molecular biology would believe that the vast majority of polynucleotides which meet the structural limitations of the claims would not meet the functional limitations. Therefore, the presence of the functional limitations in these claims, in the absence of a description of those structural or chemical features needed to provide the recited functions, constitutes nothing more than a wish to know the identity of any polynucleotide meeting the limitations of the claim. The description in the instant specification of that single species of polynucleotide belonging the large genus of polynucleotides encompassed by the claims does not provide adequate written support for the claimed genus.

10) Claims 34 to 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention because the limitations “greater than 64% sequence homology” and “no greater than 50% amino acid sequence identity” have no support in the specification as filed. These limitations are new matter. Applicant’s reference to Table 8 on page 123 of the instant specification as supporting these limitations does not provide an adequate basis for them. The description of an amino acid sequence having the equivalent of 64% sequence identity to a referenced amino acid sequence does not serve as a basis for the new inventive concept of a sequence having “greater than” or “less than” the value presented in that table.

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11) Claims 34 to 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11.1) Claims 34 to 44 are vague and indefinite in reference to the term “beta2” for those reasons of record as applied to claims 5 to 9, 11, 12, 14 to 27 in section 7 of Paper Number 6 and claims 5, 6, 8, 9, 11, 12, 14 to 27, 31 and 32 in section 9.2 of Paper Number 8. As stated therein, the properties identified by Applicant in traversal of this rejection are not identified in the instant specification as exclusive to a protein encompassed by the term “beta2”. Because the instant specification does not identify that property or combination of properties **which is unique to and, therefore, definitive of a “beta2” subunit an artisan can not determine if a compound which meets all of the other limitations of a claim, such as claim 34, would then be included or excluded from the claimed subject matter by the presence of this limitation.**

11.2) Claims 36 and 37 are vague and indefinite because there is no antecedent basis for “the substantially pure DNA of claim 34”, which is drawn to a “substantially pure polynucleotide”.

11.3) Claims 39 to 41 are vague and indefinite because the limitation “stringent conditions” is conditional and no single set of conditions which define this limitation in the capacity in which it is used in these claims is provided by the specification. In traversing this rejection Applicant has failed to identify any support in the instant specification for the term “stringent conditions”. The text referred to by Applicant makes no reference to “stringent conditions”.

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11.4) Claims 42 to 44 are vague and indefinite because each of the limitations "50% amino acid sequence identity", "44% amino acid sequence identity" and "64% amino acid sequence identity" requires a reference to one or more specific amino acid sequences. The limitations "alpha2, alpha3, alpha4 and alpha5", "beta3" and "beta4" do not correspond to specific amino acid sequences. Further, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of an alpha2, alpha3, alpha4, alpha5, beta3 or beta4 receptor subunit, it is not possible to determine the metes and bounds of these claims.

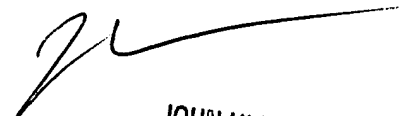
11.5) Applicant's arguments filed 08 October of 2002 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800